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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,816	02/28/2002	Tomas Cihlar	240.1PCD	3270

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EXAMINER
CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,816	CIHLAR, TOMAS	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,17 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14, 17 and 18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims I-7 and 10, drawn to an isolated nucleic acid comprising an hOAT sequence, such as SEQ ID No. 1, a vector comprising said nucleic acid, and a recombinant cell comprising said vector, classifiable in classes 536 and 435, subclasses 23.5 and 320.1, respectively.

II. Claims 8 and 9, drawn to an isolated hOAT polypeptide, classified in class 530, subclass 350.

III. Claim 11, drawn to a transgenic animal expressing hOAT, classified in class 800, subclass 13.

IV. Claims 12, 17 and 18, drawn to a method for screening candidate hOAT agonist or antagonist by contacting the candidate with hOAT nucleic acid and detect the effect on hOAT nucleic acid expression, classified in class 435, subclass 6.

V. Claims 12, 17 and 18, drawn to a method for screening candidate hOAT agonist or antagonist by contacting the candidate with hOAT polypeptide and detect the effect on hOAT polypeptide biological activity, classified in class 435, subclass 4.

VI. Claim 13, drawn to a method of identifying one or more allele and/or isoform of hOAT polypeptide sequence in individual humans, classified in class 435, subclass 7.1.

VII. Claim 14, drawn to a method of identifying nucleic acid variation in hOAT coding sequence in individual humans, classified in class 435, subclass 6.

2. Claims 12, 17 and 18 link(s) inventions IV and V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 12, 17 and 18.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

3. Groups I-III are distinct from each other because they are drawn to different compositions having different chemical structure, physical properties and biological functions, and requiring separate search: nucleic acids, polypeptides and transgenic animals. Search for nucleic acids does not require search for polypeptides and transgenic animals, and search for polypeptides does not require search for nucleic acids and transgenic animals and so forth. Since the classification for each is different, the search for each group would not be coextensive. Therefore, they are patentably distinct from each other. Similarly, group III is patentably distinct from groups IV-VIII for the same reasons.

Groups IV and V are distinct from each other because they are drawn to distinct methods which differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. A method of detecting hOAT nucleic acid

expression and a method of detecting hOAT polypeptide biological activity are drawn to different scientific considerations and they differ in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. Thus, groups IV and V are patentably distinct from each other. Similarly, groups VI and VII are distinct from each other for the same reasons.

Groups IV-V and groups VI-VII are distinct from each other because they are drawn to distinct methods which differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. Since they have different classifications, the search for each group would not be coextensive. Therefore, they are patentably distinct from each other.

Inventions I-II and IV-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used to produce recombinant polypeptides or used as a probe for hybridization. The polypeptide can be used to produce antibodies and purification of said antibodies. They have different classifications and require separate search. Thus, groups I-II are patentably distinct from groups IV-VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.